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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,797

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Niel F. Starksen

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

09/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/656,797	Applicant(s) STARKSEN, NIEL F.	
	Examiner KATHERINE M. DOWE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45, 47 and 49-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-34, 37-45 and 51-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35, 36, 47, 49 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/11/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 11, 2009 has been entered.
2. Claims 1-45, 47, and 49-60 are currently pending, with claims 1-34, 37-45, and 51-60 withdrawn from consideration.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

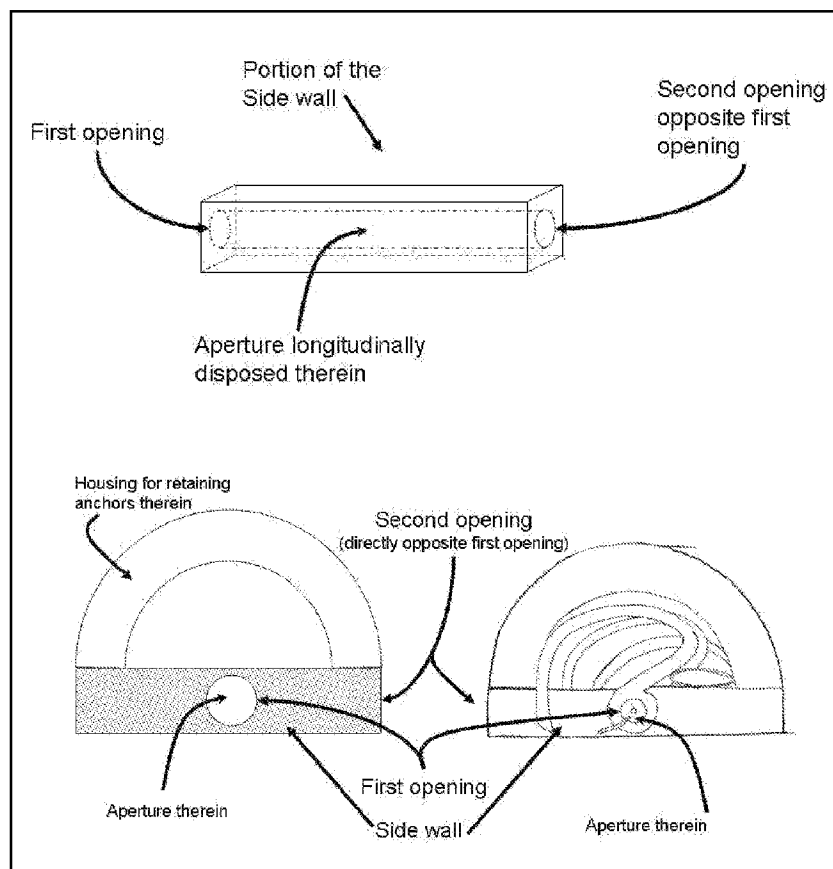
4. Claims 35, 36, 47, 49, 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient support in the disclosure for the following limitation,

"wherein the side wall has at least one aperture disposed longitudinally therein the aperture having a first opening and a second opening, and wherein when the

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device is in the first configuration the aperture retains a mandrel therein" (claim 35, lines 5-8).

In the remarks filed May 11, 2009, Applicant argues the limitation, "wherein the side wall has at least one aperture disposed longitudinally therein the aperture having a first opening and a second opening" should be interpreted such that the "aperture" is equivalent to a lumen within the side wall of the housing, separate from the main lumen of the housing. And the "first and second openings" should be interpreted as proximal and distal openings of the lumen. See Applicant's sketch/annotated drawings provided in the remarks filed May 11, 2009 copied below:



Applicant's annotated drawings presented on pages 11-12 of Remarks filed May 11, 2009

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The specification of the instant application merely recites,

"Hooks 232 may be coupled to the device via a pivot mandrel 236, so that when balloon 234 is inflated, as in FIG. 5B, hooks 232 pivot around mandrel 236 to enter tissue of the valve annulus VA. Hydraulically driving curved hooks 232 in this way closely replicates the motion of a surgeon manually driving a suture needle into tissue and allows hooks 232 to be driven strongly into the tissue of the valve annulus VA. After hooks 232 are engaged with the valve annulus VA, they may be cinched, using the tether (not shown), to decrease the diameter of the annulus and thus the valve. The housing, the balloon 234 and the pivot mandrel 236 may be withdrawn before or after cinching." (page 16, ¶0054).

and

"Typically, hook delivery device 260 will include an elongate housing or shaft 261, which will house a series of hooks 264 coupled to housing 261 via a pivot mandrel 266 and coupled to one another via a tether 268. Housing 262 will also include one or more expandable balloons 262 for driving hooks 264... Pivot mandrel 268 may also have any suitable configuration and be made of any suitable material. In one embodiment, mandrel 268 is made of a metal such as stainless steel, titanium or nitinol." (page 17, ¶0057).

The specification does not recite any type of aperture within the side wall of the device, separate from the main lumen of the housing. Furthermore, the drawings do not clearly depict such an aperture. The specification additionally does not recite any structural relationship between the mandrel and the housing, other than that the mandrel couples the hooks, or anchors, to the device. The drawings appear to show the mandrel is within the main lumen of the housing device, not within a separate lumen within the side wall of the housing. The Examiner additionally notes neither the specification nor the drawings depict or describe the proximal end of the device, and thus there is no support for a second opening opposite the first opening, whether or not the Applicant is referring to the lumen within the side wall of the device or if the Applicant is referring to the main lumen of the housing that contains the anchors and the tether.

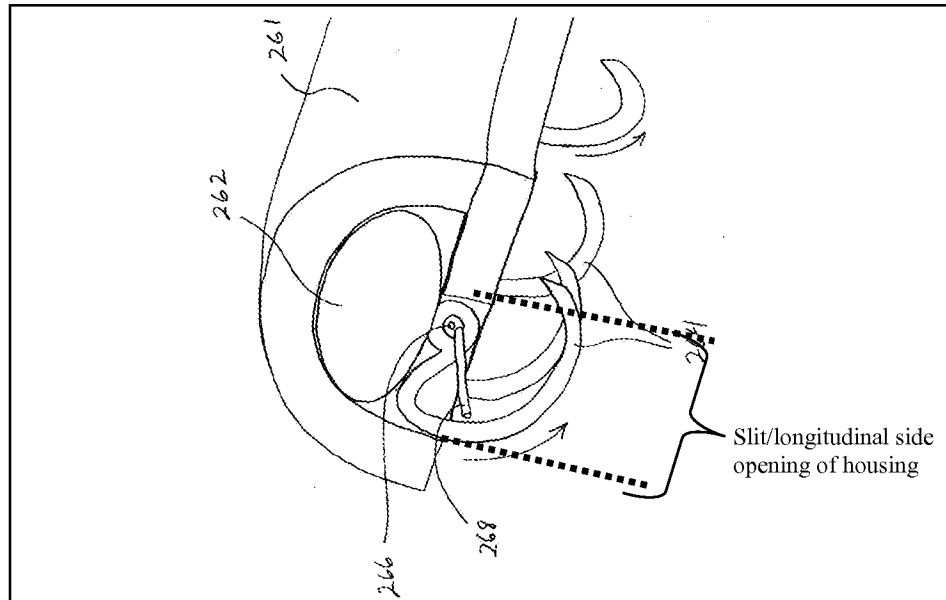
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5. Claims 35, 36, 47, 49, 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following limitation is not enabled by the disclosure:

"wherein the side wall has at least one aperture disposed longitudinally therein the aperture having a first opening and a second opening, and wherein when the device is in the first configuration the aperture retains a mandrel therein" (claim 35, lines 5-8).

As shown above, Applicant argues the "aperture" should be interpreted as a lumen within the side wall of the housing, separate from the main lumen of the housing. It is unclear how the device will operate as disclosed if the mandrel may be housed within its own aperture within the sidewall of the housing. The ends of the hooks that should be coupled to the mandrel are not capable of encircling the mandrel if the mandrel is within its own aperture separate from the main lumen of the housing. The only way the hooks may be coupled to the mandrel as disclosed is if the hooks and mandrel are contained within the same aperture. However, if the hooks are contained within the lumen of the side wall, the hooks are not capable of pivoting about the mandrel to engage tissue. Figures 5A-5D and 8 clearly show the anchors, tether, and mandrel are housed within a main lumen of the housing, wherein the housing comprises a slit or side opening for the anchors to be pivoted out through and engage tissue. See annotated portion Figure 8 below:

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Examiner's annotated version of Figure 8 of instant application

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 35, 36, 47, 49, 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what structure corresponding to the structure disclosed in Applicant's figures and specification

Applicant is referring with the limitation,

"wherein the side wall has at least one aperture disposed longitudinally therein the aperture having a first opening and a second opening, and wherein when the device is in the first configuration the aperture retains a mandrel therein" (claim 35, lines 5-8).

No such aperture appears to be disclosed. The specification does not recite the term "aperture" or "opening", much less a "first opening" and a "second opening". The drawings do not clearly show the claimed aperture or openings either. Furthermore, if

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the mandrel is contained within an aperture, or lumen, of the side wall separate from the main lumen of the housing, it is unclear how the anchors may be coupled to the mandrel and how the anchors may pivot about the mandrel to engage tissue.

Drawings

8. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the aperture disposed longitudinally within the side wall of the housing having first and second openings and a mandrel retained therein must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 35, 36, 47, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayhurst (US 5,810,848). Regarding claims 35 and 36, Hayhurst discloses a device capable of performing a procedure on annular tissue of a heart comprising an elongate body, or rigid shaft, having a housing (20) at the distal end. The housing has a housing body (24) retaining at least one tethered anchor (anchors 44, 46, 48, and 50 and tether 52). The housing body comprises a side wall spanning a longitudinal length thereof, wherein the side wall has at least one aperture (22) disposed longitudinally therein having a first opening and a second opposite opening. In a first configuration, the aperture retains a mandrel (62) therein, wherein the mandrel is capable of preventing release of the at least one tethered anchor. In a second configuration, the mandrel is withdrawn to release the at least one tethered anchor from the housing body (col 3, ll 52-67).

Regarding claim 47, the anchor is a straight barbed hook (Fig 13).

Regarding claim 49, the anchor has a cylindrical cross section (col 2, ln 65), which implies curved edges, and thus may alternatively be interpreted as a curved hook, or curved anchor. The mandrel may be interpreted as a pivot mandrel since the anchors pivot with respect to the mandrel to engage tissue.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayhurst (US 5,810,848), as applied to claim 35 above, further in view of Kniazuk (US 3,727,614). Hayhurst discloses the invention substantially as claimed as shown above. However, Hayhurst does not disclose a balloon. Kniazuk discloses a device comprising a piston (25), or rod, and bellows (22), or a balloon and teach the position of the rod is driven by the inflation/deflation of the balloon (Fig 2; col 3, ll 49-56). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Hayhurst to include a balloon that is inflated to advance the mandrel (62) and/or the supply rod (60) which drive the tethered anchors into tissue. With a controlled inflation rate, the force applied to the mandrel and the supply rod to deliver the anchors would be constant and could be set to a specific value. Thus, the modification would improve the delivery of the anchors by eliminating the variable force possible when different users apply different forces to the handle mechanism.

Response to Arguments

13. Applicant's arguments filed May 11, 2009 have been fully considered but they are not persuasive.

14. Regarding the rejection of claims 35, 36, 47, 49, and 50 under 35 U.S.C. 112, first and second paragraphs, presented in the Final Rejection mailed March 11, 2009, Applicant argues an aperture inherently has two openings. The Examiner respectfully disagrees. The common definition of "aperture" is a single opening, or window.

However, if an aperture is interpreted as a lumen, as it appears Applicant is arguing, the lumen may only have one opening, such as a hole. Or the aperture may be completely enclosed with no openings, such as a hollow cylindrical container with closed ends. An aperture with two openings is merely one example of an aperture. An aperture does not *inherently* have two openings. The Examiner notes the proximal end of the device is not sufficiently discussed in the specification or depicted in the drawings and thus it is not inherent that there is an open proximal end.

15. Applicant additionally argues the aperture described in claim 35 cannot be reasonably construed to be the housing lumen and that the claim language clearly distinguishes the housing body lumen from the aperture disposed longitudinally in the housing body side wall. Applicant argues the portion of the housing body that retains the anchor is distinct from the aperture in the side wall that retains the mandrel. The Examiner respectfully disagrees with Applicant's remarks; however, the interpretation is moot in view of the new ground(s) of rejection.

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16. Applicant's arguments with respect to claims the rejection of claims 35, 36, 47, 49, and 50 as being anticipated by Adams et al. (US 7,004,958) have been considered but are moot in view of the new ground(s) of rejection in view of Hayhurst (US 5,810,848).

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Katherine Dowe
September 11, 2009

/K. M. D./
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734